Listing of the Claims

This listing of claims will replace all prior versions of claims in the application:

1. (original) A penetration composition for non-invasive translocation of at least one effector across a biological barrier, said composition comprising:

(a) a therapeutically effective amount of said effector;

(b) a counter ion to the effector; and

(c) a penetrating peptide.

2. (original) The penetration composition of claim 1 further comprising a pharmaceutically acceptable excipient, pharmaceutically acceptable carrier, or a combination thereof.

3. (original) The penetration composition of claim 1, wherein said composition is contained within a capsule.

4. (original) The penetration composition of claim 1, wherein said composition is in the form of a tablet.

5. (original) The penetration composition of claim 1, wherein said composition is enteric-coated.

6. (original) The penetration composition of claim 1, wherein said composition is in the form selected from the group consisting of an aqueous dispersion, a suspension and an emulsion.

7. (original) The penetration composition of claim 1, wherein said compositio n is in the form of a cream.

8. (original) The penetration composition of claim 1, wherein said composition is in the form of an ointment.

9. (original) The penetration composition of claim 1, wherein said composition is in the form of a suppository.

10. (currently amended) The penetration composition of claim 1, wherein said at least one effector is ~~a cationic or~~ an ~~anionic~~ impermeable molecule.

11. (currently amended) The penetration composition of claim 10, wherein said ~~cationic or anionic~~ impermeable molecule is a bioactive molecule used to treat a metabolic disorder.

12-14. (canceled)

15. (currently amended) The penetration composition of claim 11, wherein said bioactive molecule is selected from the group consisting of: insulin; ~~erythropoietin (EPO);~~ glucagon- like peptide 1 (GLP-1); αMSH; parathyroid hormone (PTH); growth hormone; and calcitonin~~; interleukin-2 (IL-2); α1- antitrypsin; granulocyte/monocyte colony stimulating factor (GM-CSF); granulocyte colony stimulating factor (G-CSF); T20; anti- TNF antibodies; interferon α; interferon β; interferon γ; lutenizing hormone (LH); follicle- stimulating hormone (FSH); enkephalin; dalargin; kyotorphin; basic fibroblast growth factor (bFGF); hirudin; hirulog; lutenizing hormone releasing hormone (LHRH) analog; brain- derived natriuretic peptide (BNP); and neurotrophic factors~~.

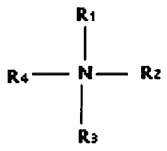
16-24. (canceled)

25. (currently amended) The penetration composition of claim 1, wherein said counter ion is ~~an anionic or~~ a cationic amphipathic molecule.

26-27. (canceled)

28. (original) The penetration composition of claim 25, wherein said cationic amphipathic molecule is a quaternary amine comprising a hydrophobic moiety.

29. (original) The penetration composition of claim 28, wherein said quaternary amine has the general structure of:



wherein R1, R2, R3 and R4 are alkyl or aryl residues.

30. (original) The penetration composition of claim 29, wherein said quaternary amine is a benzalkonium derivative.

31-38. (canceled)

39. (original) The penetration composition of claim 1, wherein said composition further comprises a polyanionic molecule.

40. (original) The penetration composition of claim 39, wherein said polyanionic molecule is phytic acid.

41. (original) The penetration composition of claim 1, further comprising a surface active agent.

42. (original) The penetration composition of claim 41, wherein said surface active agent is selected from the group consisting of a poloxamer, Solutol HS15, Cremophore and bile acids.

43. (original) The penetration composition of claim 1, wherein said composition is dissolved in an at least partially water soluble solvent.

44. (original) The penetration composition of claim 43, wherein said at least partially water soluble solvent is selected from the group consisting of: n-butanol; isoamyl (=isopentyl) alchohol; iso-butanol; iso-propanol; propanol; ethanol; ter-butanol alcohols; polyols; DMF; DMSO; ethers; amides; esters; and mixtures thereof.

45. (original) The penetration composition of claim 1, wherein any one or more of the components of the composition is lyophilized.

46. (currently amended) The penetration composition of claim 1, wherein said composition further comprises a hydrophobic carrier comprising at least one hydrophobic molecule[[s]], wherein said molecule[[s]] ~~are~~ is aliphatic~~, aromatic, or combinations thereof~~.

47. (currently amended) The penetration composition of claim 46, wherein said aliphatic hydrophobic molecules are ~~selected from the group consisting of~~ fatty acids~~, monoglycerides, di- glycerides, triglycerides, ethers, and cholesterol esters of fatty acids~~.

48-49. (canceled)

50. (original) The penetration composition of claim 1, further comprising at least one protective agent.

51. (currently amended) The penetration composition of claim 50, wherein said protective agent is a protease inhibitor selected from the group consisting of: aprotinin; Bowman-Birk inhibitor; and soybean trypsin inhibitor~~; chicken ovomucoid; chicken~~

~~ovoinhibitor; human pancreatic trypsin inhibitor; camostate mesilate; flavonoid inhibitors; antipain; leupeptin; paminobenzamidine; AEBSF; TLCK; APMSF; DFP; PMSF; poly(acrylate) derivatives; chymostatin; benzyloxycarbonyl-Pro-Phe-CHO; FK-448; sugar biphenylboronic acids complexes; β-phenylpropionate; elastatinal; methoxysuccinyl-Ala-Ala-Pro-Valchloromethylketone (MPCMK); EDTA; chitosan-EDTA conjugates; amino acids; dipeptides; tripeptides; amastatin; bestatin; puromycin; bacitracin; phosphinic acid dipeptide analogues; α-aminoboronic acid derivatives; Na-glycocholate; 1,10-phenantroline; acivicin; L-serine-borate; thiorphan; and phosphoramidon~~.

52. (original) The penetration composition of claim 1, wherein the penetrating peptide comprises at least one amino acid sequence selected from the group consisting of:

a) $(BX)_4Z(BX)_2ZXB$;

b) $ZBXB_2XBXB_2XBX_3BXB_2X_2B_2$;

c) $ZBZX_2B_4XB_3ZXB_4Z_2B_2$;

d) $ZB_9XBX_2B_2ZBXZBX_2$;

e) $BZB_8XB_9X_2ZXB$;

f) $B_2ZXZB_5XB_2XB_2X_2BZXB_2$;

g) $XB_9XBXB_6X_3B$;

h) $X_2B_3XB_4ZBXB_4XB_nXB$;

i) $XB_2XZBXZB_2ZXBX_3BZXBX_3B$;

j) $BZXBXZX_2B_4XBX_2B_2XB_4X_2$;

k) $BZXBXZX_2B_4XBX_2B_2XB_4$;

l) $B_2XZ_2XB_4XBX_2B_5X_2B_2$;

m) $B_qX_tZB_mX_qB_4XBX_nB_mZB_2X_2B_2$;

n) $B_2ZX_3ZB_mX_qB_4XBX_nB_mZB_2X_2B_2$;

o) $X_3ZB_6XBX_3BZB_2X_2B_2$; and

p) at least 12 contiguous amino acids of any of peptides a) through o)

wherein

q is 0 or 1;

m is 1 or 2;

n is 2 or 3;

t is 1 or 2 or 3; and

X is any amino acid;

B is a hydrophobic amino acid; and

Z is a charged amino acid;

wherein said penetrating peptide is capable of translocating across a biological barrier.

53. (previously presented) The penetration composition of claim 52, wherein the penetrating peptide comprises an amino acid sequence selected from the group consisting of:

a) SEQ ID NO: 24;

b) a variant of SEQ ID NO: 24, wherein one or more amino acid residues in said variant differs from the amino acid sequence of said penetrating peptide, provided that said variant differs in no more than 15% of amino acid residues from said amino acid sequence;

c) a fragment of SEQ ID NO: 24; and

d) a peptide comprising at least 12 contiguous amino acids of SEQ ID NO:24.

54. (original) The penetration composition of claim 53, wherein the fragment is at least 10 amino acids in length.

55. (original) The penetration composition of claim 53, wherein the amino acid sequence of said variant comprises a conservative amino acid substitution.

56. (original) The penetration composition of claim 53, wherein the amino acid sequence of said variant comprises a non-conservative amino acid substitution.

57. (original) The penetration composition of claim 53, wherein the penetrating peptide is further modified, via one or more peptidic bonds, to enable protection from gastrointestinal proteolysis.

58. (original) The penetration composition of claim 57, wherein one or more amino acid residues in said variant is replaced by a non- naturally occurring amino acid, selected from

the group consisting of: D-amino acids; norleucine; norvaline; homocysteine; homoserine; ethionine; and compounds derivatized with an amino-terminal blocking group including t-butyloxycarbonyl, acetyl, methyl, succinyl, methoxysuccinyl, suberyl, adipyl, azelayl, dansyl, benzyloxycarbonyl, fluorenylmethoxycarbonyl, methoxyaselayl, methoxyadipyl, methoxysuberyl, and a 2,3-dinitrophenyl group.

59. (original) The penetration composition of claim 57, wherein one or more peptide bonds have been replaced with an alternative type of covalent bond to form a peptide mimetic.

60-63. (canceled)

64. (original) The penetration composition of claim 52, wherein penetrating peptide is the peptide of SEQ ID NO: 24 or at least 12 contiguous amino acids thereof.

65. (original) The penetration composition of claim 52, wherein the penetrating peptide is less than 30 amino acids long.

66. (original) The penetration composition of claim 52, wherein the penetrating peptide is less than 25 amino acids long.

67. (original) The penetration composition of claim 52, wherein the penetrating peptide is less than 20 amino acids long.

68. (original) The penetration composition of claim 52, wherein said penetrating peptide further contains lysine residues, interspaced by glycine, alanine or serine residues, added at the C-terminus of the penetrating peptide, and wherein the free amino groups of said lysine residues are acylated.

69. (original) The penetration composition of claim 68, wherein acylation utilizes long-chain fatty acids selected from the group of: stearoyl, palmitoyl, oleyl, ricinoleyl, lauroyl and myristoyl.

70-76. (canceled)

77. (currently amended) The composition of claim 2, wherein the composition further comprises a mixture of at least two substances selected from the group consisting of a non-ionic detergent, ~~an ionic detergent,~~ a protease inhibitor, and a reducing agent.

78. (original) The composition of claim 77, wherein the non- ionic detergent is a poloxamer or Solutol HS15.

79. (original) The composition of claim 78, wherein the poloxamer is pluronic F-68.

80-81. (canceled)

82. (currently amended) The composition of claim 77, wherein the protease inhibitor is selected from the group consisting of: aprotinin; Bowman-Birk inhibitor; and soybean trypsin inhibitor~~; chicken ovomucoid; chicken ovoinhibitor; human pancreatic trypsin inhibitor; camostate mesilate; flavonoid inhibitors; antipain; leupeptin; *p*-aminobenzamidine; AEBSF; TLCK; APMSF; DFP; PMSF; poly(acrylate) derivatives; chymostatin; benzyloxycarbonyl-Pro-Phe-CHO; FK-448; sugar-biphenylboronic acids complexes; β-phenylpropionate; elastatinal; methoxysuccinyl-Ala-Ala-Pro-Val-chloromethylketone (MPCMK); EDTA; chitosan-EDTA conjugates; amino acids; dipeptides; tripeptides; amastatin; bestatin; puromycin; bacitracin; phosphinic acid dipeptide analogues; α-aminoboronic acid derivatives; Na-glycocholate; 1,10-phenantroline; acivicin; L-serine-borate; thiorphan; and phosphoramidon~~.

83. (original) The composition of claim 77, wherein the reducing agent is NAC.

84-89. (canceled)

90. (original) A kit comprising, in one or more containers, a therapeutically or prophylactically effective amount of the composition of claim 2.

91-96. (canceled)

97. (previously presented) An isolated peptide comprising an amino acid sequence of SEQ ID NO:24, wherein said peptide is derived from a human neurokinin receptor, and wherein said peptide is characterized by the ability to penetrate biological barriers *in vivo*.

98. (canceled)

99. (original) The penetration composition of claim 1, wherein said penetrating peptide further comprises a chemical modification.

100. (canceled)

101. (original) The penetration composition of claim 99, wherein the chemical modification comprises the attachment of one or more polyethylene glycol residues to the penetrating peptide.